



TTB Formulation Seminar Agenda - May 3, 2006

- 9:00 am Introductory Remarks
 Bill Foster, Asst. Administrator, *Headquarter Operations*
- 9:10 am General Remarks
 Janet Scalese, Chief, *Nonbeverage Products Laboratory*
- 9:20 am Nonbeverage Products Laboratory Overview
 Marsha Galicia, Chemist, *Nonbeverage Products Laboratory*
- 10:10 am Break
- 10:30am Reducing Returns: Getting Your Formulas Through the First Time
 Edward Limowski, Chemist, *Nonbeverage Products Laboratory*
- 11:30 am Lunch
- 12:30 pm Preparing Formulas for Submission to the NPL
 John Shifflett, Chemist, *Nonbeverage Products Laboratory*
- 1:30 pm The Future of the NPL
 Dawit Bezabeh, Senior Chemist, *Nonbeverage Products Laboratory*
- 2:00 pm Break
- 2:15 pm Introduction to Beverage Formulations
 Roberta Sanders, Program Manager, *Beverage Formulation Office*
- 3:00 pm Wine Formulations
 Stephen Robey, Formula Specialist, *Beverage Formulation Office*
- 3:45 pm Distilled Spirits Formulations
 Michael Warren, Formula Specialist, *Beverage Formulation Office*
- 4:15 pm Malt Beverage Formulations
 Roberta Sanders, Program Manager, *Beverage Formulation Office*

Nonbeverage Products Laboratory

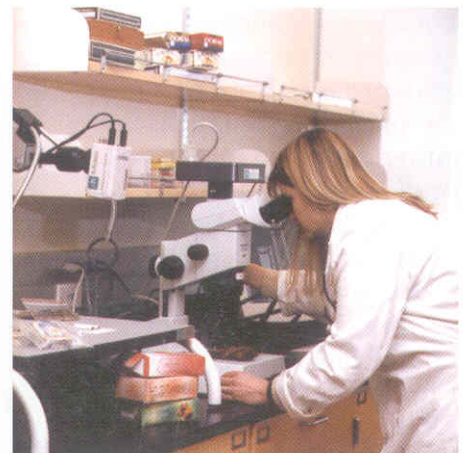


The Nonbeverage Products Laboratory analyzes and evaluates nonbeverage alcohol and tobacco products. Nonbeverage alcohol products fall into two categories: Specially Denatured Alcohol (SDA) and Drawback Alcohol.

SDA products are not intended for internal human use. They must be unfit for beverage purposes and potable alcohol cannot be recovered from them. Tax is not paid on this alcohol. Examples of SDA products are hairspray, deodorant, and hand sanitizers.

Drawback products must be a food, flavor, medicine or perfume. The products are intended for consumption but not as beverages. Therefore they must be unfit for beverage purposes. Tax is paid on this alcohol when purchased by the manufacturer. After the laboratory approves the formula, the company can claim a return on most of the tax paid.

Tobacco products are analyzed at the laboratory for tax classification. The laboratory works closely with ATF and other agencies to identify counterfeit products.



Primer for Naming Nonbeverage Products

In general, products are named based on the U.S. Food and Drug Administration's (FDA) regulations. Those guidelines are listed first. If flavors are used in alcoholic beverages, TTB has slightly more liberal guidelines for labeling of flavors used in alcoholic beverages. Those are listed second.

FDA Guidelines

- Natural Flavors: must contain a natural source of the named material and must be an all-natural product. Any flavor materials present must be derived from the named ingredient. For example, a natural strawberry flavor must contain a natural source of strawberry and all flavor materials must be derived from strawberry.
- Natural Flavors WONF: must contain a natural source of the named material but may also contain other natural flavor materials. These other natural flavors do not need to be derived from the named material. For example, a natural strawberry flavor WONF must contain a natural source of strawberry but may also contain natural flavor chemicals not necessarily derived from strawberry (e.g. natural ethyl butyrate).
- Natural & Artificial Flavors: must contain a natural source of the named material but may also contain artificial flavor materials.
- Natural Type Flavors, Natural Bases and Natural Keys: natural flavors that do not contain the named ingredient. For example, natural strawberry type flavor contains all natural ingredients but does not contain a natural source of strawberry.
- Artificial Flavors: predominant flavor is from artificial ingredients.

TTB Guidelines

- Natural & Artificial Flavors with 0.1% artificial topnote: flavors containing not more than 0.1% artificial topnote are considered natural when used in alcoholic beverages. The calculation of the amount of artificial material does not include artificial vanillin, ethyl vanillin, artificial maltol nor ethyl maltol.
- When flavors are submitted for drawback of tax, the name should comply with FDA requirements (i.e. Natural & Artificial) even though TTB will consider them natural when they are used in alcoholic beverages.
- Natural & Artificial Flavors with greater than 0.1% artificial topnote: considered for alcoholic beverage labeling purposes to be artificial.
- Other considerations: TTB has limitations for artificial vanillin, ethyl maltol, artificial maltol and ethyl maltol in alcoholic beverages. If these limitations are exceeded, the finished beverage will be considered an artificial product.

Vanillin: 40 ppm
Ethyl vanillin: 16 ppm
Maltol: 250 ppm
Ethyl maltol: 100 ppm

Keep in mind that these limitations are in the finished alcoholic beverage; not in the flavor. The actual amount present in the beverage will be calculated based on the use rate of the flavor.

- Wines containing < 7% by volume ethanol are subject to the FDA labeling guidelines listed above.

Guidelines for Nonbeverage Product Formulation

In the absence of materials that will make the product more palatable (sugar, glycerin, high fructose corn syrup, etc.), the following commonly used ingredients when present in the stated amounts will, in most instances, make a product unfit for beverage purposes. This list is intended only as a guide and is not applicable to all products.

Ingredient

Amount

Citric acid

If the ethanol content is < 30% v/v, acid should be = $0.1 \times \text{ethanol} + 0.5$. If ethanol content is > 30% v/v, acid should be $0.1 \times \text{ethanol}$. Reported in g/100 mL (*the ethanol content is defined as the upper end of the range in item 10 on TTB Form 5154.1*)

Salt (sodium chloride)

3.21 g salt/100 mL @ 45% v/v ethanol

Vanillin

1 av. oz./gal @ 30% v/v ethanol

Ethyl vanillin

0.4 av. oz./gal @ 30% v/v ethanol

Propylene glycol

Equal amounts by volume of ethanol and propylene glycol (*the amount of ethanol is defined as the upper end of the range in item 10 on TTB Form 5154.1*)

Ethyl acetate

2% by volume @ 90% v/v ethanol

Maltol

5% by weight @ 90% v/v ethanol

Essential oils

Most essential oils are unfit at 3% wt/wt in 90% v/v ethanol. Many 1% wt/wt solutions of essential oils are unfit. An exception is anise oil.

What is density?

Density is how heavy something is for its size (how much it weighs divided by how big it is). So, something that is small and heavy has a high density.

Density is mass divided by volume. It's usually measured in grams per milliliter or pounds per gallon. To work out the density of something, divide mass (how much it weighs), by volume (how much space it takes up).

Example:

A gallon of water weighs 8.33 pounds. The density is 8.33 pounds/gallon.

It is important to note that density varies with temperature (TTB uses densities at 60°F). The gauging manual provides densities for ethanol:water solutions across a broad temperature range:

http://www.ttb.gov/foia/gauging_manual.htm

Some important densities to remember:

Ingredient	Pounds/gallon	grams/milliliter (also kilograms/liter)
Water	8.3282	1.0000
200 proof Ethanol	6.6110	0.7936
190 Proof Ethanol	6.7943	0.8141
Propylene Glycol	8.6300	1.0360

What is specific gravity?

The specific gravity of a substance is a comparison of its density to that of water. It is calculated by dividing the density of the material by the density of water at 4 °C. Because specific gravity is a ratio, it is a unitless quantity.

Important unit conversions

1 gallon = 3785 milliliters

3.785 liters = 1 gallon

1 gallon = 128 fluid ounces

1 pound = 453.5924 grams

1 pound = 16 ounces

The following is a link to the NIST website for unit conversions:

<http://physics.nist.gov/cuu/Reference/unitconversions.html>

Some sample calculations are provided on the following websites (TTB does not endorse these websites or their contents):

<http://blowers.chee.arizona.edu/cooking/units.html>

<http://www.ncsu.edu/felder-public/kenny/papers/units.html>

Coloring Materials

Many alcohol beverage products contain coloring agents. Coloring agents are added to impart color which is not natural to the product. There are two categories of coloring agents that are used: FDA Certified Colors and Non-certified Colors. Certified colors are synthetic dyes approved by the FDA for use in beverage products. The non-certified colors are natural coloring agents approved for use in alcohol beverages. Below is a list of coloring agents which may be used in beverage products.

Certified Colors

FD&C Blue #1	FD&C Blue #2
FD&C Green #3	FD&C Red #3
FD&C Red #40	FD&C Yellow #5**
FD&C Yellow #6	

**Must be specifically declared on the beverage label.

Non-Certified Colors

Annatto Extract	Caramel
Carmines (Cochineal Extract)	Beta Carotene
Elderberry Extract	Grapeskin Extract
Paprika	Saffron
Titanium Dioxide	Turmeric
Beet Extract	

Flavoring Substances and Adjuvants Subject to Limitation or Restriction

Acacia - Gum arabic.....	20%
Acetic acid.....	0.15%
Aconitic acid.....	0.002%
Adipic acid.....	0.02%
Agar.....	0.25%
Ammonium alginate.....	0.1%
Artemisia - Wormwood.....	finished prod. thujone free
Bakers yeast extract.....	5%
Beeswax yellow & white.....	0.002%
Benzoic acid.....	0.1%
BHA - 0.02% edible fats & oils.....	0.5% of volatile essential oils
BHT (edible fats & oils).....	0.02%
Bitter Almond oil.....	Free from prussic acid
Brominated vegetable oil - BVO.....	15 ppm
Caffeine.....	200 ppm
Calcium acetate.....	0.0001%
Calcium alginate.....	0.3%
Calcium chloride.....	0.05%
Calcium phosphate, dibasic.....	0.5%
Calcium phosphate, monobasic.....	0.02%
Calcium phosphate, tribasic.....	0.5%
Calcium pyrophosphate.....	0.2%
Calcium sulfate.....	0.07%
Camphor tree.....	Safole free
Caprylic acid.....	0.001%
Cedar, white (arborvitae)leaves & twigs.....	finished prod. thujone free
Cherry pits.....	25 ppm prussic acid
Cherry - laurel leaves.....	25 ppm prussic acid
Cinchona, red & yellow bark	
Total alkaloids.....	83 ppm
Corn silk & corn silk extract.....	4 ppm
Dithiols.....	1 ppm
EDTA.....	25 ppm
Elder tree leaves.....	25 ppm prussic acid in flavor
Ester gum	
(Glycerol ester of wood rosin).....	100 ppm
Ethyl trans 2 cis 4 decadienoate.....	10 ppm
Ethyl formate.....	0.01%
Guar gum.....	0.5%
Gum ghatti.....	0.1%
Gum tragacanth.....	0.1%
Isopropyl citrate.....	0.02%
Karaya gum.....	0.002%
Licorice and licorice derivatives	
as Glycyrrhizin.....	0.1%
Locust bean gum.....	0.5%

Malic acid	0.7%
Mannitol	2.5%
Methylcellulose	0.003%
Methylparaben	0.1%
Mustard (allyl isothiocyanate)	0.02%
Mustard (brown/black/oriental)	1.0%
Mustard (yellow/white)	1.7%
Oak moss	finished prod thujone free
Oak chips	Labeling requirement
Oil of Rue	4 ppm
Peach leaves	25 ppm prussic acid
Potassium alginate	0.01%
Potassium metabisulfite	0.06%
Potassium sorbate	0.1%
Propylene glycol	5%
Propylparaben	0.1%
Quinine	83 ppm
Quinine bisulfate (as quinine)	83 ppm
Quinine hydrochloride (as quinine)	83 ppm
Quinine sulfate (as quinine)	83 ppm
Rue	2 ppm
Sassafras leaves	safrole free
Silicone	10 ppm
Sodium acid pyrophosphate	0.3%
Sodium alginate	1.0%
Sodium aluminosilicate	2.0%
Sodium benzoate	0.1%
Sodium calcium aluminosilicate hydrated	2.0%
Sodium carboxymethylcellulose	0.8%
Sodium hexametaphosphate	0.05%
Sodium phosphate, dibasic	0.5%
Sodium phosphate, monobasic	0.08%
Sodium phosphate, tribasic	0.07%
Sodium thiosulfate (alc. bev. only)	0.00005%
Sorbic acid	0.2%
Sorbitol	12%
St. Johnswort leaves, flowers & caulis	hypericin free
Stannous chloride	0.0015%
Stearyl citrate	0.15%
Sucrose acetate isobutyrate (SAIB)	300 ppm
Sulfur dioxide	10 ppm
Sulfuric acid	0.014%
Tagetes	as oil only
Tannic acid	0.015%
Tansy	finished prod. thujone free
Woodruff, sweet	5 ppm coumarin
Yarrow	finished prod. thujone free

Top 10 Reasons for Formula Returns

1. A sample is needed
2. Natural and artificial components are not identified
3. The final yield is missing
4. The manufacturing process is missing
5. The alcohol content by analysis is inconsistent with what is stated on the formula
6. Subformula (intermediate) has not been submitted, or it has been returned to the submitter
7. The predominant ingredient in a chemical grouping has not been quantified and/or identified
8. The botanical source of natural vanillin has not been declared
9. The volume equivalent for ingredients containing alcohol is missing
10. Limited ingredients are not disclosed

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